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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,435	01/18/2002	Gideon Bollag	ONYX1028/1028div/Formal D	7344
7590 01/16/2004			EXAMINER LAMBERTSON, DAVID A	
Gregory Giotta, Ph.D. Vice President and Chief Legal Counsel ONYX Pharmaceuticals, Inc. 3031 Research Drive Richmond, CA 94806			ART UNIT 1636	
DATE MAILED: 01/16/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/054,435

Applicant(s)

BOLLAG ET AL.

Examiner

David A. Lambertson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-6, 68 and 69 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2, 3, 6, 68 and 69 is/are rejected.
- 7) ☒ Claim(s) 4 and 5 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Receipt is acknowledged of a reply to the previous Office Action, filed October 22, 2002. Amendments were made to the claims. Specifically, claims 1 and 7-67 were cancelled, and new claims 68-69 were added.

Claims 2-6, 68 and 69 are pending and under consideration in the instant application. Any rejection of record in the previous Office Action, mailed April 23, 2003, that is not addressed in this action has been withdrawn.

Applicant is hereby notified that the examination of the Application has transferred from William Sandals to Examiner David A. Lambertson, Ph.D. All further correspondence should be directed to the new Examiner.

Because this Office Action only maintains rejections set forth in the previous Office Action and/or sets forth new rejections that are necessitated by amendment, this Office Action is made FINAL.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. §§ 119(e) and 120 as follows:

It is noted that this application appears to claim subject matter disclosed in prior Application No. 09/079,812 (now US Patent 6,340,575), filed May 15, 1998 and US Provisional Application 60/049,879, filed June 17, 1997. A reference to the prior application must be inserted as the first sentence of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e) or 120. See 37 CFR 1.78(a). For benefit

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claims under 35 U.S.C. 120, the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. Also, the current status of all nonprovisional parent applications referenced should be included.

If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director

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may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

In the previous Office Action, the details regarding perfecting Applicant's priority claim were omitted by the previous Examiner. However, the conditions set forth above still must be met. As the priority claim set forth in the response to the previous Office Action was not accompanied by the necessary petition and fee, the priority claim has NOT been entered into the specification. As such, Applicant's priority claim is granted only as far as the filing date of the instant Application, January 18, 2002.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 68 and 69 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. **This is a new rejection that is necessitated by amendment.**

The test of enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the specification coupled with information known in the art without undue experimentation (*United States v. Telectronics*, 8 USPQ2d 1217 (Fed. Cir. 1988)). Whether undue experimentation is needed is not based

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upon a single factor but rather is a conclusion reached by weighing many factors. These factors were outlined in *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Inter. 1986) and again in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988), and the most relevant factors are indicated below:

Nature of the invention. The nature of the invention is any Rac-GEF protein that is encoded by a polynucleotide having 95% identity to SEQ ID NO: 1. There is no functional limitation associated with the protein that is encoded by the polynucleotide sequence.

Scope of the invention. The scope of the invention is very broad, encompassing a number of Rac-GEF proteins encoded by polynucleotides with homology/hybridization capacity towards SEQ ID NO: 1, wherein the proteins do not have any relevant biological activity.

State of the art. The prior art is silent with regard to the nature of SEQ ID NO: 1, and is therefore so as it regards Rac-GEF proteins that are encoded by said polynucleotides.

Therefore, the skilled artisan cannot consult the prior art with regard to making or using a Rac-GEF protein that is encoded by a polynucleotide that hybridizes or is 95% identical to SEQ ID NO: 1, wherein the encoded protein does not have a relevant biological activity.

Number of working examples and Guidance provided by applicant. Applicant provides guidance with regard to making and using a Rac-GEF protein having guanine nucleotide exchange activity, a specific binding affinity for a guanine nucleotide exchange activity or a cellular oncogenic transforming activity, but provides no guidance with regard to a Rac-GEF without such a relevant biological activity. Therefore, the

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skilled artisan could not rely on the instant specification to make and use a protein encoded by a polynucleotide that hybridizes or is 95% identical to SEQ ID NO: 1, wherein the encoded protein does not have a relevant biological activity.

Unpredictability of the art and Amount of experimentation required. The claimed invention is unpredictable in many areas. First, the skilled artisan can have no idea what biological activities are set forth in a Rac-GEF protein encoded by a polynucleotide that hybridizes or is 95% identical to SEQ ID NO: 1 in the absence of an indication of a relevant biological activity. Therefore, the skilled artisan would be required to perform empirical trial and error experimentation in order to determine the relevant biological activity of such a Rac-GEF protein. Second, the skilled artisan could not be reasonably apprised of how to use a protein for which no biological activity is recited. This too would require a great deal of undue and unpredictable trial and error experimentation to determine how use a Rac-GEF protein that is encoded by a polynucleotide that hybridizes or is 95% identical to SEQ ID NO: 1, but has no clear biological activity. As a result of this unpredictability, the claims are not enabled as instantly presented.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 69 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. **This is a new rejection that is necessitated by amendment.**

The term "stringent conditions" (with regard to nucleic acid hybridization) in claim 69 is a relative term which renders the claim indefinite. The term "stringent

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conditions" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is noted that the instant specification provides an insufficient definition for the term "stringent conditions" on pages 13-14. The definition is insufficient because it is, in itself, indefinite. The definition contains a range within a range (i.e., at least about 95%, preferably 97%; see for example line 28, page 13 to line 2, page 14 of the instant specification), which is indefinite because it is unclear which of the limitations of the range applies to "stringent conditions" in the instant claim. Furthermore, the definition sets forth the conditions by describing an example of the conditions considered to be "stringent" (see for example lines 2-6 on page 14 of the instant specification). This is also indefinite because it is unclear what other conditions are also an example of "stringent." If this is what is meant by "stringent conditions," applicant should incorporate the conditions into the instant claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2, 3 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Davies *et al.* as set forth in the previous Office Action. **This rejection is maintained for reasons set forth in the previous Office Action.**

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Claims 2 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Chuang *et al.* as set forth in the previous Office Action. **This rejection is maintained for reasons set forth in the previous Office Action.**

Claims 2, 3 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,994,070 as set forth in the previous Office Action. **This rejection is maintained for reasons set forth in the previous Office Action.**

Response to Arguments Concerning Claim Rejections - 35 USC § 102

Applicant's arguments filed October 22, 2003 have been fully considered but they are not persuasive. Applicant's arguments concern the following points as it regards each of the rejections under 35 USC 102(b); the arguments will be addressed collectively with regard to the rejections:

1. Applicant's invention contains features that are not disclosed by any of the references cited above in the rejections under 35 USC § 102(b). In particular, Applicant purports that the references do not teach that the Rac-GEFs have the capacity to transform cells (i.e., cellular oncogenic transforming activity; see for example page 7, second and third full paragraphs of Applicant's arguments).
2. Applicant asserts that the references do not specifically teach SEQ ID NO: 2, which is allegedly claimed by all of the rejected claims (see for example the top of page 7 of Applicant's arguments).

Applicant's arguments are not convincing for the following reasons:

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1. First, none of the claims requires that the claimed Rac-GEF polypeptide have the capacity to transform cells. This is because this characteristic is recited *in the alternative* along with several other characteristics, including guanine nucleotide exchange activity and a specific binding affinity for a guanine nucleotide depleted Rac; therefore, meeting any of these limitations would be sufficient to meet the limitations set forth in the claims. It is noted that there is no argument that any of the references fails to teach each and every one of the characteristics recited in the alternative. Second, Applicant's assertion that the references do not teach this characteristic for their disclosed Rac-GEF polypeptides is incorrect. For instance, US Patent No. 5,944,070 clearly states at column 34, lines 62-65 that, "TRIO is also recognized as being involved in the activation of oncogenes, such as c-fos. In addition, as described in the appended examples, TRIO has been demonstrated to induce transformation of cells" (see also the Examples). Thus, in at least the US Patent No. 5,994,070 reference, it is taught that the Rac-GEF has the capacity to oncogenically transform cells.

2. Applicant's assertion that the 102(b) references do not teach SEQ ID NO: 2 specifically is irrelevant to the claims indicated as rejected because there is no recitation of SEQ ID NO: 2 as a limitation of the rejected claims. For the record, it is noted that claims 4 and 5, which do recite SEQ ID NO: 2 as a limitation, are not rejected by any of the aforementioned references. Therefore, applicant's argument is moot.

In conclusion, Applicant's arguments are insufficient to overcome the rejection of claims 2, 3 and 6 under 35 USC § 102(b) because the arguments focus on limitations that are not present in the claims, and because Applicant misrepresents what is taught by the applied references.

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Allowable Subject Matter

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (703) 308-8365. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David A. Lambertson, Ph.D.
AU 1636


JAMES KETTER
PRIMARY EXAMINER